BRANAN BMC MEDICAL CORP

NOV 21 2008

510(k) SUMMARY

This summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) number is: K082508

Submitter

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Date Prepared

August 25, 2008

Contact Person

Raphael Wong
President

Product Names

Fastect® II BUP Drug Screen Dipstick
QuickTox® Drug Screen Dipcard

Common Name

Immunochromatographic test for the qualitative detection of Buprenorphine in urine.

Classification Panel

Buprenorphine Test Systems

Product Code

DJG

Classification Number

21 CFR, 862.6350

Device Classification

The Buprenorphine test systems are classified as Class II devices with moderate complexity. These tests are used to provide only a preliminary result. All positive test results obtained with these devices must be confirmed by another test method, preferably GC/MS or LC/MS confirmatory analysis.

Intended Use

The Fastect® II BUP Drug Screen Dipstick and the QuickTox® Drug Screen Dipcard devices are chromatographic immunoassays for the qualitative detection of Buprenorphine in human urine at a cut-off concentration of 10 ng/ml. These tests are screening devices and provide only a preliminary result. All positive test results obtained should be confirmed by another test method, preferably GC/MS or LC/MS analysis. The Fastect® II BUP Drug Screen Dipstick and the QuickTox® Drug Screen Dipcard devices are intended for professional use only. They are not intended for over-the-counter sale to non-professionals.

Description

The Fastect® II BUP Drug Screen Dipstick and QuickTox® Drug Screen Dipcard are based on the principle of highly specific immunochemical reactions between antigens and antibodies. Both devices utilize a competitive immunoassay procedure in which an immobilized drug conjugate competes with the drug present in urine for limited antibody binding sites. If Buprenorphine is present in the urine, it competes with the immobilized drug conjugate for the limited binding sites on the colored antibody colloidal gold conjugate. When a sufficient amount of drug is present, the drug will saturate the antibodies, and the colored colloidal gold conjugate cannot bind to the drug conjugate immobilized on the membrane. Thus, the absence of the purple-red band at the test region indicates a preliminary positive result. However, if there is no drug present to compete for the binding sites of the colored colloidal gold conjugate, it binds to the immobilized drug conjugate to form a visible purple-red band at the test region of the membrane. Thus, the presence of a purple-red band at the test region indicates a negative result. The Fastect® II BUP Drug Screen Dipstick and QuickTox® Drug Screen Dipcard devices are standardized to detect Buprenorphine in human urine at a cut-off concentration of 10 ng/ml. These tests can be performed without the use of any additional instruments.

A control band with a different antigen/antibody reaction is added to the immunochromatographic membrane strip and should always appear regardless of the presence of drug or metabolite. The appearance of the control band during testing indicates that the test has completed and the test is valid.

Safety and Effectiveness Data

Accuracy

A total of 90 urine specimens were evaluated with the Fastect® II BUP Drug Screen Dipstick and QuickTox® Drug Screen Dipcard devices. Of the 90 urine specimens, 50 urine samples were clinical specimens previously analyzed by GC/MS with known Buprenorphine concentrations. Approximately 10% were near-negative samples and at least 10% of the clinical urine samples were near-positive. When near-negative and near-positive clinical urine samples could not be easily obtained, more concentrated clinical urine samples were diluted to make these samples. Both the Fastect® II BUP Drug Screen Dipstick and QuickTox® Drug Screen Dipcard devices were compared with the ACON® BUP One Step Buprenorphine Test Device as well as against the values obtained through GC/MS analysis. The following shows the results obtained from this study:

Fastect® II BUP Drug Screen Dipstick Test

	Negative (<50%)	GC/MS Near Negative (50% to C/O)	GC/MS Near Positive (C/O to +50%)	GC/MS High Positive (>+50%)	% Agreement
Positive (+)	0	3	6	33	100%
Negative (-)	43	5	0	0	94%

QuickTox® Drug Screen Dipcard Test

	Negative (<50%)	GC/MS Near Negative (50% to C/O)	GC/MS Near Positive (C/O to +50%)	GC/MS High Positive (>+50%)	% Agreement
Positive (+)	0	3	6	33	100%
Negative (-)	43	5	0	0	94%

Performance Characteristics and Other Information

The performance characteristics of the Fastect® II BUP Drug Screen Dipstick and QuickTox® Drug Screen Dipcard devices were verified by sensitivity, precision, specificity, cross-reactivity, interference (pH and Specific Gravity), stability, and optimal read time studies. Results from these studies show that the above-mentioned devices are reliable and meet performance claims when used according to the instructions provided in the Package Insert.

Conclusion

The performance characteristics studies performed demonstrate substantial equivalency between the Fastect® II BUP Drug Screen Dipstick and QuickTox® Drug Screen Dipcard devices and ACON® BUP One Step Buprenorphine Test Device with the same cut-off concentration of 10 ng/ml. We have demonstrated that these tests are safe and effective in qualitatively detecting Buprenorphine at a cut-off concentration of 10 ng/ml. Therefore these tests are suitable for professional use only.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Branan Medical Corporation
c/o Mr. Raphael Wong
President
140 Technology Drive, Suite 400
Irvine, CA 92618

NOV 21 2008

Re: k082508
Trade Name: Fastect® II BUP Drug Screen Dipstick QuickTox® Drug Screen Dipcard
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate Test System
Regulatory Class: Class II
Product Codes: DJG
Dated: August 25, 2008
Received: September 02, 2008

Dear Mr. Wong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
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Enclosure

Indications for Use

510(k) Number (if known): K082508

Device Name: Fastect® II BUP Drug Screen Dipstick

QuickTox® Drug Screen Dipcard

Indications for Use:

The Fastect® II BUP Drug Screen Dipstick and QuickTox® Drug Screen Dipcard devices are rapid immunochromatographic immunoassays for the qualitative detection of Buprenorphine in human urine at a cut-off concentration of 10 ng/ml. The devices are intended for professional use only. They are not intended for over-the-counter sale to non-professionals.

The Fastect® II BUP Drug Screen Dipstick and QuickTox® Drug Screen Dipcard tests are used to obtain visual, qualitative results. A more specific alternate method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS are the preferred confirmatory methods.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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